CLAIMS

1. (Currently amended) A plurality of storage ~~Storage~~ stable pharmaceutical ~~formulation~~ formulations, each formulation comprising at least two pharmaceutically active compounds in a substantially non-swellable diffusion matrix, characterized in that the matrix is determined with respect to its essential release characteristics by ethylcellulose or an ethylcellulose-based polymer and at least one fatty alcohol and that the active compounds are released from the substantially non-swellable diffusion matrix of each formulation in a sustained, invariant and independent manner, and characterized in that it comprises as the pharmaceutically active compounds at least one opioid analgesic selected from the group ~~comprising~~ consisting of morphine, oxycodone, hydromorphone, propoxyphene, nicomorphine, dihydrocodeine, diamorphine, papaveretum, codeine, ethylmorphine, phenylpiperidine~~, and derivatives thereof~~, methadone, dextropropoxyphene, buprenorphine, pentazocin, tilidine, tramadol and hydrocodone and at least one opioid antagonist, selected from the group ~~comprising~~ consisting of naltrexone, naloxone, nalmefene, nalorphine, nalbuphin, naloxonazinene, methylnaltrexone, ketylcyclazocine, norbinaltorphimine, naltrindol, 6-β-naloxol and 6-β-naltrexol.

2. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 1, characterized in that the fatty alcohol ~~comprises~~ is one or more fatty alcohols selected from the group consisting of lauryl alcohol, myristyl alcohol, stearyl alcohol, cetylstearyl alcohol, ceryl alcohol and cetyl alcohol ~~lauryl, myristyl, stearyl, cetylstearyl, ceryl and/or cetylalcohol~~.

3. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 2, characterized in that ~~the~~ each formulation comprises ethylcellulose.

4. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 3, characterized in that the ~~formulation does~~ formulations do not comprise ~~relevant amounts of~~ alkaline ~~and/or~~ or water-swellable substances.

5. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 4, characterized in that ~~the~~ each formulation comprises one or more ingredients selected from the group consisting of fillers, lubricants, flowing agents ~~and/or~~ and plasticizers.

6. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 5, characterized in that ~~the~~ one or more fillers are selected from the group ~~comprising~~ consisting of sugars, starches ~~and~~ , starch hydrolysates ~~thereof~~, sugar alcohols~~,~~ and poorly soluble calcium salts ~~and/or povidone~~.

7. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 5, characterized in that ~~it~~ each formulation comprises one or more ingredients selected from the group consisting of magnesium stearate, calcium stearate ~~and/or~~, calcium laureate ~~and/or~~ and fatty acids.

8. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 5, characterized in that ~~it~~ each formulation comprises ~~a~~ one or more flowing agents selected from the group consisting of highly dispersed silica, talcum, corn starch, magnesium oxide, magnesium stearate and ~~calciumstearate~~ calcium stearate.

9. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 5, characterized in that ~~it~~ each formulation comprises dibutyl sebacate as a plasticizer.

10. (Currently amended) ~~Pharmaceutical preparation~~ A plurality of pharmaceutical formulations according to claim 5, characterized in that ~~the~~ each formulation ~~can be stored~~ is storage stable over a period of at least two years under standard conditions of ~~(~~60% relative humidity and 25° C~~)~~.

11. Canceled

12. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 5, characterized in that the opioid analgesic and the opioid antagonist are present in the form of their pharmaceutically acceptable free base or ~~salts~~ a pharmaceutically acceptable salt.

13. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 12, characterized in that ~~the~~ each formulation comprises oxycodone and naloxone, and wherein oxycodone is present in an amount raging from 10 mg to 150 mg, and naloxone is present in an amount ranging from 1 mg to 50 mg per unit dosage.

14. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 13, characterized in that ~~it~~ each formulation comprises oxycodone and naloxone in a weight ratio ranging from about 25:1 to about 1:1.

15. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim ~~12~~ 1, characterized in that ~~it~~ each formulation contains oxycodone and naloxone with oxycodone being present in an amount ranging from 10 mg to 150 mg, and naloxone is present in an amount ranging from about 1 mg to about 50 mg.

16. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 13, characterized in that ~~the~~ each formulation is in ~~the~~ a form selected from the group consisting of a tablet, ~~preferably~~ a multi-layered tablet, a capsule, a dragée, a granulate ~~and/or~~ and a powder.

17. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 16, characterized in that ~~the~~ each pharmaceutical ~~preparation~~ formulation is suitable for administration by a route selected from the group consisting of oral, nasal ~~and/or~~ and rectal ~~application~~.

18. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 16, characterized in that ~~the~~ each formulation is produced by build-up and/or break-down granulation.

19. (Currently amended) ~~Pharmaceutical formulation~~ A plurality of pharmaceutical formulations according to claim 17, characterized in that ~~the~~ each formulation is produced by extrusion.

20 – 23 Canceled.

24. (Currently amended) ~~Storage~~ A plurality of storage stable pharmaceutical formulations, each formulation having an effective amount of an opioid agonist and an opioid antagonist in a substantially non-swellable and non-erosive diffusion matrix, whose release characteristics are determined by amounts of ethylcellulose or an ethylcellulose-based polymer and at least one fatty alcohol.

25. (Currently amended) ~~Storage~~ A plurality of storage stable pharmaceutical ~~formulation~~ formulations according to claim 24, each formulation having an effective amount of oxycodone and naloxone, with oxycodone being present in an amount ranging from 10 mg

to 150 mg, and naloxone is present in an amount ranging from 1 mg to 50 mg per unit dosage.

26. (Currently amended) ~~Storage~~ A plurality of storage stable pharmaceutical ~~formulation~~ formulations according to claim 24, each formulation having an effective amount of oxycodone and naloxone, wherein oxycodone and naloxone are present in a weight ratio ranging from 25:1 to 1:1.

27. (Withdrawn) Method for producing a formulation according to claim 26, characterized in that production is effected by granulation, preferably build-up and/or break-down granulation.

28. (Withdrawn) Method for producing a formulation according to claim 26, being an extrusion method, wherein counter-rotating or co-rotating single or multiple screw extruders with/without kneading elements are used.

29. (Withdrawn) Method according to claim 28, being an extrusion method wherein counter-rotating twin-screw extruders are used.

30. (Withdrawn) Method according to claim 28, characterized in that the temperature of the heating zones of the extruders is from about 20° to about 120° C.

31. (Withdrawn) Method according to claim 28, characterized in that the diameter of the nozzle on the extruder is between about 1 mm to about 10 mm.

32. (Withdrawn) Method according to claim 28, characterized in that the resulting temperature in the extruder does not influence the stability of the active compounds.

33. (Withdrawn) Method of producing a pharmaceutical dosage form for the treatment of opioid-induced side effects, characterized in that the pharmaceutical dosage form comprises a pharmaceutical formulation according to claim 5.

34. (Withdrawn) Method according to claim 33, characterized in that the preparation is used for treatment of opioid-induced obstipation.

35. (Withdrawn) Method of producing a pharmaceutical dosage form for the treatment of idiopathic syndromes, characterized in that the pharmaceutical dosage form comprises a pharmaceutical formulation according to claim 5.

36. (Withdrawn) Method according to claim 35, characterized in that the preparation is used for treatment of irritable bowel syndrome, treatment of idiopathic pruritus or pruritus due to cholestasia and/or renal dysfunction.

37. (Withdrawn) Method according to 33, characterized in that the matrix is a substantially non-swellable diffusion matrix whose release characteristics are determined by amounts of ethylcellulose or an ethylcellulose-based polymer and of at least one fatty alcohol.

38. (Withdrawn) Method according to 37, characterized in that the preparation comprises from about 1 mg to about 50 mg naloxone.

39. (Withdrawn) Method according to claim 38, characterized in that naloxone is present in the form selected from the pharmaceutically acceptable and equally active derivatives the free base, salts and the like.

40. (Withdrawn) Method according to claim 39, characterized in that the matrix is produced by extrusion.

41. (Currently amended) A plurality of pharmaceutical ~~formulation~~ formulations according to claim 4, characterized in that the ~~formulation does~~ formulations do not comprise ~~relevant amounts of derivatives of~~ acrylic acid ~~and/or~~ or hydroxyalkylcelluloses.

42. (Currently amended) A plurality of pharmaceutical ~~formulation~~ formulations according to claim 6, characterized in that the fillers are one or more fillers selected from the group ~~comprising~~ consisting of lactose, glucose, saccharose, micro-crystalline cellulose, cellactose, sorbitol, mannitol, calcium ~~hydrogenphosphate~~ hydrogen phosphate, ~~dicalciumphosphate~~ dicalcium phosphate~~,~~ and ~~tricalciumphosphate~~ tricalcium phosphate ~~and povidone~~.

43. (Currently amended) A plurality of pharmaceutical ~~formulation~~ formulations according to claim 7, characterized in that ~~it~~ each formulation comprises stearic acid.

44. (Currently amended) A plurality of pharmaceutical ~~formulation~~ formulations according to claim 12, characterized in that the opioid analgesic and the opioid antagonist are present in ~~the form~~ one or more forms selected from the group consisting of the hydrochloride, sulfate, bisulfate, tartrate, nitrate, citrate, bitartrate, phosphate, malate, maleate, hydrobromide, hydroiodide, fumarate ~~or~~ and succinate.

45. (Currently amended) A plurality of pharmaceutical ~~formulation~~ formulations according to claim 13, characterized in that ~~the~~ each formulation comprises oxycodone and naloxone, and wherein oxycodone is present in an amount raging from 10 mg to 80 mg and naloxone is present in an amount ranging from 1 mg to 50 mg per unit dosage.

46. (Currently amended) A plurality of pharmaceutical ~~formulation~~ formulations according to claim 14, characterized in that ~~it~~ each formulation comprises oxycodone and naloxone in a weight ratio ranging from 5:1 to 1:1.

47. (Currently amended) A plurality of storage stable pharmaceutical ~~formulation~~ formulations according to claim 19, wherein the matrix of each formulation is formed by melt extrusion.

48. (Currently amended) A plurality of storage stable pharmaceutical ~~formulation~~ formulations according to claim 25, each formulation having an effective amount of oxycodone and naloxone, with oxycodone being present in an amount ranging from 10 mg to 80 mg and naloxone being present in an amount ranging from 1 mg to 50 mg per unit dosage.

49. (Currently amended) A plurality of storage stable pharmaceutical ~~formulation~~ formulations according to claim 26, each formulation having an effective amount of oxycodone and naloxone, wherein oxycodone and naloxone are present in a weight ratio ranging from 5:1 to 1:1.

50. (Withdrawn) The method according to claim 30, characterized in that the temperature of the heating zones of the extruders is from about 50° to about 70° C.

51. (Withdrawn) The method according to claim 31, characterized in that the diameter of the nozzle on the extruder is between about 3 mm to about 5 mm.

52. (Withdrawn) The method according to claim 34, characterized in that the preparation is used for treatment of opioid-induced pruritus.

53. (Withdrawn) The method according to 38, characterized in that the preparation comprises from about 5 mg to about 20 mg naloxone.

54. (Withdrawn) The method according to claim 39, characterized in that naloxone is present in the form of the hydrochloride, sulfate, bisulfate, tartrate, nitrate, citrate, bitartrate, phosphate, malate, maleate, hydrobromide, hydroiodide, fumarate or succinate.